Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Empowering people with type 2 diabetes family-based approach - central

Protocol summary

Summary

Diabetes mellitus is a chronic disease with high prevalence and is a growing concern in the world. Several factors in the care of people with chronic diseases such as diabetes that the concept of health literacy known as an important factor on diabet mellitus . Although diabetes is one of the most important socio-economic and health concerns and help diabetics patients for good glycemic control and prevention of complications of disease is related to the patients health literacy and self efficacy . Considering the fact that the relationship between support and family education and diabetes, few studies about patients with type 2 diabetes and most of the research done in this regard on children and youths in Iran, also according to the characteristics unique Iranian families and the culture of governing, little research has been reported in this case.The aim of this study was to determine the effect of family-centered empowerment model on health literacy and self-efficacy in people with type 2 diabetes. Inclusion criteria: age between 20 to 60 years old; no history for mental disorders; diagnosis for diabetes at lease for one year; ability for reading and writing; not attending in another study by Patients and families; living with family; ability to talk and communicate with the family; no serious or debilitating complications of diabetes such as kidney failure and blindness and patient and caregiver agree to participate in the research. Exclusion criteria: no desire to continue cooperation and participate inthe study; be suffering from mental illness or other chronic diseases; not having caregiver for the patients. In this study, the study population of diabetic patients referred to Imam Ali Shahr-e-Kord clinic was selected from among which 80 patients with type 2 diabetes were selected randomly and then assigned randomly into two groups of control and intervention (each group was 40 patients) . In control group, routine training are received in the control group, but in the intervention group, family-based care is provided to the patient and the main care giver of the patient (family member), in 6 sessions Family-centered empowerment will take place at intervals of one week and 90 minutes each session. The data gathering tool in this study was a questionnaireof health literacy and self-efficacy in diabetic patients who evaluated the level of health literacy and self-efficacy in the three stages before, immediately and three months after the intervention. Data is analyzed using software 23 and statistical tests such as paired t-test, independent t-test, chi-square

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201609252861N13**
Registration date: **2017-10-19, 1396/07/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-19, 1396/07/27

Registrant information

Name

Reza Masoodi

Name of organization / entity

Nursing department, Shahrekord University of Medical Science,

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 5654

Email address

masoodi@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2016-09-25, 1395/07/04

Expected recruitment end date
2016-12-24, 1395/10/04

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Empowering people with type 2 diabetes family-based approach - central

Public title
The Effect of program based onthe family-centered model on health literacy and self-efficacy of people with type 2 diabetes

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: age between 20 to 60 years old; no history for mental disorders; diagnosis for diabetes at lease for one year; ability for reading and writing; not attending in another study by Patients and families; living with family; ability to talk and communicate with the family; no serious or debilitating complications of diabetes such as kidney failure and blindness and patient and caregiver agree to participate in the research.
Exclusion criteria: no desire to continue cooperation and participate in another study during the study; be suffering from mental illness or other chronic diseases; not having caregiver for the patients.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord University of Medical Sciences

Street address
Shahrekord University of Medical Sciences

City
Shahrekord

Postal code

Approval date
2016-07-03, 1395/04/13

Ethics committee reference number
IR.SKUMS.REC1395.89

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E10-14

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Health literacy

Timepoint
Pre intervention, 2 mounths after intervention

Method of measurement
Health literacy questinnaire

2

Description
Self efficacy

Timepoint
Pre intervention, 2 mounths after intervention

Method of measurement
Self efficacy questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
This program is performed for the intervention group during six sixty-minute sessions and with a constant research team including internist, nurse internist and researcher..In each session, based on the content,paid attention to provide educational content, discuss patient experiences and treatments and illnesses problem. This care program is presented during discussion sessions

Also, through group discussion and telephone counseling, they will be in possession of an educational CD and some of them will be introduced to hospitals or charity associations.The researcher will discuss the treatment and care situation, the defects of their treatment and care knowledge and their support needs in this area, and provide guidance and action.Complete the questionnaire before and immediately after the intervention three months after the intervention.

Category

Behavior

2

Description

The control group only receives routine care and education. A researcher to observe ethical standards, after the end of the study, for the intervention group, invites control group patients to attend training sessions in a telephone call and Educational CDs (content provided during the Empowerment Program) will be delivered to them.The researcher's phone is also provided to them for further guidance.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic located at the Imam Ali clinic

Full name of responsible person

Fatemeh Ghasemi

Street address

Imam Ali clinic, Shariati blvd.

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shahrekord University of Medical Sciences

Full name of responsible person

Vice chancellor for research of Shahrekord University of Medical Sciences

Street address

Kashani Blvd-University Headquarters-second floor

City

Shahrekord

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research of Shahrekord University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Fatemeh Ghasemi

Position

Master Student of Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Assisstant Professor/Ph.D in Nursing Education

Other areas of specialty/work

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Person responsible for updating data

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Position
Master Student of Nursing

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty